510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:
k090389

B. Purpose for Submission:
New device

C. Measurand:
Whole blood glucose

D. Type of Test:
Whole blood glucose concentration through a quantitative amperometric assay (Glucose Oxidase)

E. Applicant:
Bestgen Biotech Corporation

F. Proprietary and Established Names:
AP-1000 Blood Glucose Monitoring System
Major Glucose Control Solution

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1345 Glucose Test System
   21 CFR 862.1660, Quality Control Material (assayed and unassayed)
2. Classification:
   Class II (assay) and Class I, reserved (controls)
3. Product code:
   NBW, Blood Glucose Test System, Over-the-Counter
   CGA, Glucose Oxidase, Glucose
   JJX, Single (specified) analyte controls (assayed and unassayed)
4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See indication for use below.

2. Indication(s) for use:
   The AP-1000 Blood Glucose Monitoring System (BGMS) is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an

aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1000 Meter is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. AP-1000 Blood Glucose Test Strips must be used with the AP-1000 Meter. Testing is done outside the body (*In Vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

The AP-1000 Blood Glucose Test Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. AP-1000 Blood Glucose Test Strips must be used with the AP-1000 Blood Glucose Meter. Testing is done outside the body (*In Vitro* diagnostic use). They are indicated for use at home (over the counter [OTC]) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

MAJOR Level I/Level II Control Solutions are for use with the AP-1000 meter and AP-1000 Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

3. Special conditions for use statement(s):
   - Not intended for diagnosis of diabetes mellitus
   - Not intended for use on neonates
   - For *in vitro* diagnostic use only
   - Not for use on critically ill patients, patients in shock, dehydrated patients or hyperosmolar patients

4. Special instrument requirements:
   AP-1000 Blood Glucose Meter

I. Device Description:

The AP-1000 Blood Glucose Monitoring System is comprised of the AP-1000 Blood Glucose Meter, AP-1000 Blood Glucose Test Strips, Major Control Solutions (2 levels) and a lancing device.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Diacare Easy Check Blood Glucose Monitoring System

2. Predicate K number(s):
   k062538

3. Comparison with predicate:

Item	Proposed Device	Easy Check (k062538)
Similarities		
Detection method	Amperometry	same
Enzyme	Glucose oxidase (*A. Niger*)	same
Mediator	Potassium hexacyanoferrate	same
Electrode	Carbon	same
Sample type	Capillary whole blood	same
Humidity range (operational)	20 to 80 %	same
Temperature range (operational)	10 to 40 °C	same
Power supply	3V lithium battery (CR2032)	same
Battery life	Over 1000 tests	same
Differences		
Test range	20 to 600 mg/dL	30 to 600 mg/dL
Hematocrit	30 to 55 %	30 to 50 %
Altitude	Up to 10,183 feet above sea level	Only at sea level
Test time	6 seconds	9 seconds
Sample volume	0.6 µl	1.5 µl
Test sample	Fingertip	Fingertip, palm and forearm
Coding	Internal code	Code card
Memory capacity	960 measurements	180 measurements
Size L x W x H (mm)	54 x 93 x 16	58 x 80 x 19
Weight (g)	53 with battery	50 without battery

Item	Proposed Control Device	Easy Check Control (k062538)
Similarities		
Number of Levels	2	same
Analyte	Glucose	same
Container	Plastic bottle with dropper tip	same
Color	Red	same
Temperature range	2 to 30 °C	same
Fill Volume	2.5 mL	same
Matrix	Buffer aqueous with glucose, sodium benzoate, viscosity modifier and non-reactive ingredient.	same
Target Population	Professional and home use	same

K. Standard/Guidance Document Referenced (if applicable):

- ISO 15197:2003, *In Vitro* Diagnostic Test Systems—Requirements for Blood Glucose Test Systems for Self Managing Diabetes Mellitus.
- IEC/EN 61010-1, Medical electrical equipment Part 1. General requirements for safety, 2001.

- IEC/EN 61601-1-2, Medical electrical equipment, Part 2. Electromagnetic compatibility—Requirements and tests, 2001.
- IEC/EN 61010-2-101, Safety particular requirements for IVD medical equipment, 2002.
- FCC 47 CFR, Part 18, 2004.
- CLSI EP5-A, Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline.
- CLSI EP6-A, Evaluation of the Linearity of Quantitative Analytical Methods; Approved Guideline.
- CLSI EP7-A, Interference Testing in Clinical Chemistry; Approved Guideline.

L. Test Principle:

The AP-1000 Blood Glucose Monitoring System uses electrochemical methodologies. The system quantitatively measures blood glucose levels using an amperometric method, which involves detecting the current produced from glucose oxidation. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the resultant current is proportional to the concentration of glucose in the specimen and the signal is converted into a readout displayed on the meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor evaluated within run and between run precision of the device using a protocol based on CLSI EP5-A. Whole blood samples spiked with six different glucose concentrations were used. Ten replicate measurements were tested for each concentration each day, using two lots of test strips and ten meters for a total of twenty days. Results for each test strip lot are summarized in the tables below:

Lot 1

Mean (mg/dL)	Within run SD (mg/dL)	Between run SD (mg/dL)	Coefficient of variation (CV %)
31.1	3.9	3.4	16.2
49.9	1.5	3.8	11.9
74.4	3.0	3.2	6.0
121	3.0	3.1	4.5
218	5.6	4.2	3.2
332	11.4	5.5	3.7

Lot 2

Mean (mg/dL)	Within run SD (mg/dL)	Between run SD (mg/dL)	Coefficient of variation (CV %)
30.4	3.9	2.8	16.2
49.9	1.5	3.9	12.3
74.4	2.9	3.2	5.9
120	3.0	2.9	4.6
219	5.8	3.0	3.0
330	10.4	6.2	3.6

In addition, the sponsor evaluated five replicates of two levels of control solutions with two test strip lots and twenty meters. Results are summarized in the following tables:

Lot 1

Level	Mean (mg/dL)	SD (mg/dL)	Coefficient of variation (CV %)
1	101.2	4.0	3.9
2	221.3	6.6	3.0

Lot 2

Level	Mean (mg/dL)	SD (mg/dL)	Coefficient of variation (CV %)
1	106.2	3.6	3.4
2	231.8	6.9	3.0

b. Linearity/assay reportable range:

The sponsor evaluated linearity of the device using a protocol based on CLSI EP6-A. Testing was performed using oxygenated venous blood samples at eleven different blood glucose levels, ranging from 20 to 726 mg/dL, tested on two lots of test strips, on ten meters in replicates of ten. The YSI 2300D STAT plus glucose analyzer was used as the reference method. The measuring range of the device is 20 to 600 mg/dL.

Linear Regression Analysis:

Lot 1: $y = 1.0375x + 3.8754$, $r^2 = 0.9991$.

Lot 2: $y = 1.0563x + 0.8588$, $r^2 = 0.9986$.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

The values for the MAJOR Control Solutions are assigned by repeat analysis using three different lots of AP-1000 test strips and five AP-1000 meters. The mean and standard deviation are used to establish the acceptable range for the strips.

Stability characteristics of the Major Glucose Control Solutions were determined using real-time studies. The unopened shelf-life is 24 months and the open vial stability is 90 days at the recommended storage of 36 °F to 86 °F.

Stability characteristics of the AP-1000 blood glucose test strips were determined using real-time studies. The unopened shelf-life is 18 months and the open vial stability is 90 days at the recommended storage of 36 °F to 86 °F.

d. Detection limit:
The measuring range of the system is 20 - 600 mg/dL. This range was verified by the linearity study (see section M.1.b.).

e. Analytical specificity:
Interference testing was performed using a protocol based on CLSI EP7-A. A blood sample was collected from a volunteer. Hematocrit was adjusted to 40 ± 2 %, and the sample was separated into two aliquots. The glucose levels were adjusted to a low (100 to 150 mg/dL) and a high (200 to 250 mg/dL) level by supplementing each sample with a 50% aqueous glucose solution. The YSI 2300D STAT plus glucose analyzer was used as a reference instrument. The following substances were evaluated, Ascorbic acid (1.2, 1.5, 2 and 3 mg/dL), Acetaminophen (2, 6, 15 and 20 mg/dL), Dopamine (3.2, 6.5, 9.7 and 13 mg/dL), Ibuprofen (4.2, 15, 30 and 40 mg/dL), L-Dopa (5 and 10 mg/dL), Tetracycline (0.4, 1.5, 3 and 4 mg/dL), Tolbutamide (10, 35, 70 and 100 mg/dL), Cholesterol (300, 350, 400 and 500 mg/dL), Creatinine (1.5, 15, 22.5 and 30 mg/dL) and Uric acid (7, 12, 16 and 20 mg/dL). Each potential interfering substance was added to an aliquot of the low glucose blood sample and to an aliquot of the high glucose to the final concentrations listed above and compared to the same sample without the potential interfering substance (control). The results are as follows:

Lot 1

Exogenous Substance			**Concentration at which drug interference was observed**	
Therapeutic levels (mg/dL)		**Maximum Test Concentration (mg/dL)**	**At low glucose level**	**At high glucose level**
Acetaminophen	1 - 2	20	2.0	15
Ascorbic acid	0.8 - 1.2	3	2.0	30
Dopamine	……	13	3.2	9.7
Ibuprofen	0.5 - 4.2	40	none	
Tetracycline	0.4	4	none	
Tolbutamide	5.3 - 10	100	none	
L-dopa	……	10	5	5

Endogenous substance (mg/dL)			Concentration at which drug interference was observed	
Physiological levels (mg/dL)		Maximum Test Concentration (mg/dL)	At low glucose level	At high glucose level
Cholesterol	300	500	none	
Creatinine	1.5	30	none	
Uric acid	7	20	7	7

Lot 2

Exogenous Substance			Concentration at which drug interference was observed	
Therapeutic levels (mg/dL)		Maximum Test Concentration (mg/dL)	At low glucose level	At high glucose level
Acetaminophen	1 - 2	20	2.0	2.0
Ascorbic acid	0.8 - 1.2	3	2.0	30
Dopamine	……	13	3.2	9.7
Ibuprofen	0.5 - 4.2	40	none	
Tetracycline	0.4	4	none	
Tolbutamide	5.3 - 10	100	none	
L-dopa	……	10	5	5
Endogenous substance (mg/dL)			**Concentration at which drug interference was observed**	
Physiological levels (mg/dL)		**Maximum Test Concentration (mg/dL)**	**At low glucose level**	**At high glucose level**
Cholesterol	300	500	none	
Creatinine	1.5	30	none	
Uric acid	7	20	7	7

Ibuprofen, Tetracycline, Tolbutamide, Cholesterol and Creatinine did not significantly interfere with the measurements (bias less than ±10%).

Acetaminophen (2 mg/dL), Ascorbic Acid (2 mg/dL at low glucose levels and 30 mg/dL at high glucose levels), Dopamine (3.2 mg/dL at low glucose levels and 9.7 mg/dL at high glucose levels), L-dopa (5 mg/dL) and Uric acid (7mg/dL) significantly interfered with the measurements (bias more than 10%).

The sponsor included the following warnings in the label:

- Therapeutic levels of acetaminophen, normal to high levels of uric acid and high levels of ascorbic acid/ vitamin C in blood may result in inaccurate glucose readings. Blood glucose readings from these cases should be interpreted with caution.
- Therapeutic levels of L-dopa or dopamine may result in inaccurate glucose readings with the system.

Hematocrit Study: the effect of hematocrit was evaluated in a study using a venous blood sample with five glucose concentrations (20, 70, 170, 285 and 600 mg/dL) and hematocrit levels adjusted to 25, 30, 40, 50, 55, 60 and 70 %. The YSI 2300D STAT plus glucose analyzer was used to check the glucose concentrations of the blood samples. Each glucose level/hematocrit combination was tested on ten meters per lot of strips (two lots of strips). The results of samples at each of the varying hematocrit levels were compared to the YSI value of the samples. The average of the measurements had a deviation less than 15% at ≥ 75 mg/dL (individual bias ranging from 0 to 17.6 %) and less than 10 mg/dL at < 75 mg/dL (individual bias ranging from 0 to 6 mg/dL) at 30 to 55% hematocrit.

The sponsor included the following warning in the label:

- Abnormal blood cell counts (hematocrit levels below 30 % and above 55 %) may cause inaccurate test results.

Altitude Study: the effect of altitude was evaluated using five venous blood samples with five glucose concentrations (56, 72, 123, 253 and 462 mg/dL) with hematocrit levels between 30 and 55 %. The YSI 2300D STAT plus glucose analyzer was used to check the glucose concentrations of the blood samples. The results of this study are acceptable: all measurements must have a deviation less than 20% at ≥ 75 mg/dL and less than 15 mg/dL at < 75 mg/dL.

The sponsor included the following statement in the label:

- Clinical testing demonstrates that altitudes up to 10,183 feet (3104 meters) above sea level do not affect results with the AP-1000 Blood Glucose Monitoring System.

Temperature and humidity studies: studies were performed to demonstrate that the meter can be used at temperatures from 10 to 40 °C and at relative humidity ranging from 20 to 80 %. A venous blood sample with three glucose concentrations (approximately 50, 100 and 250 mg/dL) was used for the studies. The YSI 2300D STAT plus glucose analyzer was used to check the glucose concentrations of the blood samples. Five meters and one lot of strips were used for each study. The results were reviewed and found to be acceptable.

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Reference Method Comparison:

This study was performed in accordance with ISO 15197 to demonstrate the accuracy of the proposed device when compared to measurements obtained with the YSI 2300D STAT plus glucose analyzer (reference method). One hundred blood samples with glucose concentrations ranging from 21.8 to 600 mg/dL were prepared by spiking a blood sample with glucose. The hematocrit was adjusted to 40 ± 2 %. The YSI 2300D STAT plus glucose analyzer was used to check the glucose concentrations of the blood samples. One meter and two lots of strips were used for the study. The study met the ISO 15197 standard where ninety-five percent (95%) of the individual glucose results shall fall within ±15mg/dL of the results at glucose concentrations <75mg/dL and within ±20% at glucose concentrations ≥75mg/dL. The results are as follows:

Linear Regression Analysis:

Lot 1: $y = 1.0106x – 1.001$, $r^2 = 0.9961$

Lot 2: $y = 1.0029x – 0.4772$, $r^2 = 0.9970$

For samples < 75 mg/dL

Lot	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	16/17 (94 %)	17/17 (100 %)	17/17 (100 %)
2	16/17 (94 %)	17/17 (100 %)	17/17 (100 %)

For samples ≥ 75 mg/dL

Lot	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
1	64/83 (77 %)	82/83 (99 %)	83/83 (100 %)	83/83 (100 %)
2	71/83 (86 %)	82/83 (99 %)	83/83 (100 %)	83/83 (100 %)

Lay-User Study:

This study was performed in accordance with ISO 15197 with 150 total patients. The 150 study participants obtained and tested their own capillary whole blood sample using the AP-1000 Blood Glucose Monitoring System (the proposed device) and only the directions in the labeling. Health care professionals then tested capillary whole blood using the proposed device and the YSI 2300D STAT plus glucose analyzer (the reference method) on the same individuals. These samples ranged in concentration from 58 to 350 mg/dL. The results met the ISO 15197 standard criteria where ninety-five percent (95%) of the individual glucose results shall fall within ±15mg/dL of the reference results at glucose concentrations <75mg/dL and within ±20% at reference glucose concentrations ≥75mg/dL. The results are as follows:

Linear Regression Analysis:

Patient vs YSI $y = 1.0102x - 1.4672$, $r^2 = 0.9877$

Healthcare professional vs YSI $y = 1.0146x - 1.2854$, $r^2 = 0.9904$

For samples < 75 mg/dL

Sample	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Patient	21/21 (100 %)	21/21 (100 %)	21/21 (100 %)
Professional	19/22 (86.4 %)	22/22 (100%)	22/22 (100%)

For samples ≥ 75 mg/dL

Sample	Within ± 5 %	Within ± 10 %	Within ± 20 %
Patient	89/129 (69.0 %)	129/129 (100 %)	129/129 (100 %)
Professional	94/128 (73.4 %)	128/128 (100 %)	128/128 (100 %)

b. Matrix comparison:
Not applicable

3. Clinical studies:

a. Clinical Sensitivity:
Not applicable

b. Clinical specificity:
Not applicable

c. *Other clinical supportive data (when a. and b. are not applicable):*
Not applicable

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:
Expected blood glucose levels for people without diabetes (referenced from the American Diabetes Association Clinical Practice Recommendations 2004, Diabetes Care, Vol. 27, Supplement 1, p. S9.)

Time	Range (mg/dL)	Range (mmol/L)
Fasting	70 to 100	3.9 to 6.1
Two hours after meals	less than 140	less than 7.8

N. Instrument Name:
AP-1000 Blood Glucose Meter

O. Systems Descriptions:

1. Modes of Operation:
   Each test strip is single use and must be replaced with a new strip for additional readings.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?:
   Yes _____ or No __X__

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:
   Yes _____ or No __X__

2. Software:
   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
   Yes __X__ or No _____

3. Specimen Identification:
   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:
   This device is intended to be used with capillary whole blood from the finger, which can be applied directly to the test strip.

5. Calibration:
   The device must be coded with the code found on the current test strip label. No further calibration is required.

6. Quality Control:
   The sponsor has two levels of controls supplied with this meter. When a test strip is inserted into the meter, each control can be measured by following the instructions for "Testing Control Samples" provided in the User's Guide for the meter. An acceptable range for each control level is printed on the test strip vial label. The user is instructed to contact the Customer Assistance line during the operational times or a healthcare provider outside the operational times if the control results fall outside these ranges.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:
Not applicable

Q. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.